

**UNITED STATES DISTRICT COURT  
DISTRICT OF NEVADA**

BARBARA HEINRICH and GREGORY  
HEINRICH,

## Plaintiffs

ETHICON, INC.; ETHICON LLC; and  
JOHNSON & JOHNSON,

## Defendants

Case No.: 2:20-cv-00166-APG-VCF

## **Order Granting in Part Defendants' Motion in Limine No. 3**

[ECF No. 131]

This case is one of many thousands of cases that were joined in multidistrict litigation

10 (MDL) in the United States District Court for the Southern District of West Virginia. The case  
11 was transferred to this court for trial in January 2020. ECF No. 69.

12 The defendants filed a motion *in limine* seeking to exclude from trial evidence that the  
13 TVT-S was voluntarily removed from the market several years after the device was implanted in  
14 plaintiff Barbara Heinrich. The defendants argue this evidence is irrelevant because it does not  
15 make it more or less probable that the TVT-S was defective. They also contend that even if there  
16 is some probative value, it is substantially outweighed by the risk of unfair prejudice. Finally,  
17 the defendants contend the evidence is inadmissible under Federal Rule of Evidence 407 as a  
18 subsequent remedial measure. The plaintiffs give several reasons why they believe the evidence  
19 is admissible.

In June 2012, Ethicon sent a letter addressed to “Surgeons” advising them that Ethicon was discontinuing the TVT-S, along with some other products. ECF No. 131-1. Ethicon gave as factors in the discontinuation decision “the commercial viability of these products” and “the availability of other treatment options.” *Id.* In the letter, Ethicon stated it wanted “to emphasize

1 that we continue to have confidence in the safety and efficacy of these products. This is not a  
2 product recall. Based on this notification, it is not necessary for patients who have received one  
3 of these products to take any action.” *Id.*

4           **A. Impeachment**

5           The plaintiffs contend that the publicly stated reasons for discontinuing the TVT-S rebuts  
6 the testimony of some of the defendants’ witnesses who have testified that the TVT family of  
7 products were the “gold standard” and set the standard of care for treatment of stress urinary  
8 incontinence. Specifically, they contend that discontinuing the product due to a lack of  
9 commercial viability and the existence of other treatment options undermines Dr. Geoffrey  
10 Hsieh’s testimony that midurethral slings are the “gold standard.”

11           Dr. Hsieh testified that all midurethral slings were the standard of care and that he stood  
12 by his decision to implant the TVT-S in Barbara Heinrich. ECF No. 148-2 at 51-52. But he did  
13 not say that the TVT-S, as opposed to other midurethral slings, was the standard of care. He  
14 stated there were “several approaches” and “several types of slings,” but the “midurethral slings  
15 as a class is the gold standard.” *Id.* at 83-84. Consequently, evidence that the TVT-S was  
16 discontinued because it was not commercially viable and there were other treatment options  
17 available does not rebut or impeach Dr. Hsieh’s testimony that midurethral slings generally were  
18 the standard of care and that there were several types of these slings and approaches. I therefore  
19 exclude the evidence of the discontinuation letter for this purpose.

20           **B. Notice**

21           The plaintiffs also argue that the discontinuation letter assured physicians and the public  
22 that the TVT-S was safe and effective and that it was not necessary for patients who were  
23 implanted with the device to take any action. The plaintiffs assert this is relevant to show that

1 well after the defendants contend that Barbara Heinrich should have learned of her claim for  
2 statute of limitations purposes, the defendants were still assuring the public and physicians that  
3 the device was safe.

4       In the first phase trial, the parties will be presenting to the jury the question of when the  
5 plaintiffs should have discovered their injuries for statute of limitations purposes. The  
6 defendants have indicated they intend to argue that a 2008 FDA public health notice put the  
7 plaintiffs on inquiry notice that the device may be the cause of the plaintiffs' injuries. *See* ECF  
8 No. 169 at 9. Evidence that the defendants continued to assure physicians and the public that the  
9 TVT-S was safe and effective long after the FDA notice is relevant to whether the plaintiffs  
10 knew or should have known of their injuries earlier. Fed. R. Evid. R. 401, 402.

11       The probative value of this evidence is not "substantially outweighed by a danger of . . .  
12 unfair prejudice, confusing the issues, misleading the jury, undue delay, wasting time, or  
13 needlessly presenting cumulative evidence." Fed. R. Evid. 403. The first-phase jury will not be  
14 assessing whether the product was defective or caused injuries to Barbara Heinrich.  
15 Consequently, the defendants will not be prejudiced, and the jury will not be confused, about  
16 whether the discontinuation is an admission of a defect or liability. I therefore deny the  
17 defendants' motion to exclude the discontinuation letter to the extent the plaintiffs seek to use it  
18 for the purpose of addressing notice and discovery in the first phase trial.

19       Finally, Federal Rule of Evidence 407 would not preclude introduction of the evidence in  
20 this context. That rule prohibits the admission of evidence of subsequent remedial measures to  
21 prove negligence, culpable conduct, a defect in a product or its design, or a need for a warning or  
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1 instruction. None of those restrictions applies to determining when the plaintiffs should have  
2 discovered their injuries in this case.<sup>1</sup>

3 **C. Punitive Damages**

4 The plaintiffs contend the discontinuation letter is relevant to punitive damages to the  
5 extent it shows that the defendants continued to reassure the public the device was safe when  
6 they knew it was unreasonably dangerous and that the defendants discontinued the device for  
7 monetary, and not safety, reasons. I defer ruling on whether the discontinuation letter would be  
8 admissible for this purpose. The first-phase trial may obviate the need to address this issue if the  
9 jury concludes the plaintiffs' claims are untimely.

10 **D. Johnson & Johnson**

11 The plaintiffs contend that the discontinuation letter shows defendant Johnson & Johnson  
12 had control over the sale, distribution, and marketing of the TVT-S and had the ability to  
13 discontinue the device earlier but failed to do so. The plaintiffs do not explain what they mean  
14 by this, but I presume it is based on the discontinuation letter identifying Ethicon as a division of  
15 Johnson & Johnson and the two individuals who signed the letter having email addresses with  
16 "jnj.com" in them. ECF No. 131-1.

17 I defer ruling on this issue because, like the punitive damages issue, this may become  
18 moot depending on how the first-phase jury rules. And I lack sufficient information about the  
19 letter, its authors, and the relationship between Ethicon and Johnson & Johnson to draw any  
20 conclusions about what the letter shows (or does not show) about Johnson & Johnson's ability to  
21 control the TVT-S's marketing, distribution, sale, or discontinuation.

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<sup>1</sup> Because I have ruled by separate order that there is no fraudulent concealment for tolling purposes in this case, the restriction on using subsequent remedial measures to show the defendants engaged in culpable conduct does not apply.

1           **E. Conclusion**

2           I THEREFORE ORDER that the defendants' motion *in limine* No. 3 (**ECF No. 131**) is  
3 **GRANTED in part.**

4           DATED this 1st day of November, 2021.

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6           ANDREW P. GORDON  
7           UNITED STATES DISTRICT JUDGE

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